

REMARKS

The application has been amended. Claims 6-8 and 14 have been cancelled. In view of the amendment and the following remarks, reconsideration is respectfully requested. Claims 1-5, 9-13, and 15-18 are currently pending.

Response to Rejections Under 35 U.S.C. §112

The Examiner has rejected claims 1-16 and 18 under 35 U.S.C §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner has further rejected claims 1-16 and 18 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, with regard to the rejections under the first and second paragraphs of 35 U.S.C. §112, the Examiner states:

“Claims 1 and 16 include the term “perimetrically non-continuous” when referring to a tubular body. This is interpreted to mean that the tubular body is non-continuous along its perimeter, i.e., along the circumference of the tubular body, since the perimeter of a tubular body is its circumference. However, the specification, on page 7, lines 19-22, defines the term “perimetrically non-continuous”, when referring to a tubular body, as a tubular body which is not substantially uninterrupted along its length. Thus, it is unclear if “perimetrically non-continuous” means non-continuous along the tubular member circumference or non-continuous along the tubular member length. In addition, it appears that second body 7 (figure 2) and second body 10 (figure 3) extend only partially in the circumferential direction since they are termed “strips” in the specification. Yet, the second bodies (e.g. second bodies 7 and 10) are referred to as a tubular bodies throughout the

specification. Thus, it is unclear from the disclosure if second bodies 7 and 10 are tubular bodies which extend completely 360 degrees circumferentially or not.”

Applicants have cancelled claims 6-8 and 14. Applicants offer the following clarifying remarks to overcome the rejections based on 35 U.S.C. §112 first and second paragraph.

The Examiner has rejected claims 1 and 16 because of the use of the term “perimetrically non-continuous”. The Examiner alleges that it is unclear if “perimetrically non-continuous” means non-continuous along the tubular member circumference or non-continuous along the tubular member length.

By way of explanation, the specification on page 7, lines 19-22 defines the term **non-continuous** as a tubular body which is ^{NOT} substantially uninterrupted long its length. The phrase “perimetrically non-continuous” has not been defined as alleged by the Examiner, but rather only the term non-continuous. The term “perimetrically non-continuous” refers to a tubular structure which is non-continuous along its circumference as postulated by the Examiner.

Applicants believe that the claims as currently standing comply with the requirements of 35 U.S.C. §112 first and second paragraphs. The rejection is therefore respectfully traversed. Reconsideration and withdrawal of the rejections under 35 U.S.C. §112 are therefore respectfully requested.

RESPONSE TO REJECTIONS UNDER 35 U.S.C. §103(a)

The Examiner has rejected claims 1-15 and 17 under 35 U.S.C. §103(a) as being unpatentable over EP 0893108 to Ray (hereinafter “Ray”). More specifically, the Examiner states:

Ray shows first substantially continuous PTFE tubular body 4, second perimetrically non-continuous tubular body (the longitudinally extending strips of the coupling member described in col. 9, lines 13-21) formed of polytetrafluoroethylene (as indicated in col. 16, lines 20-31) and support structure 6. Axial and radial compliance is obviously provided to the prosthesis due to the gaps between the strips. As to claim 3, note col. 7, lines 24-26 which indicates that the coupling member may be located on the inner rather than the outer surface of the stent. As to claim 6, note col. 10, lines 42-46.

European Patent Application No. 893,108 A2 to Ray et al. (hereinafter "Ray") discloses a kink-resistant stent/graft with an ePTFE tube, a stent and a coupling member. The coupling member in Ray is a ribbon which covers only a portion of at least one of the inner and outer surfaces of the stent and is utilized solely for securing the stent member and graft member to each other. In the preferred embodiment, the ribbon coupling member is circumferentially wound around the graft. See Figures 1A, 1B, 1C, 2, 4, 5, 6, 7, 8 of Ray.

The coupling member, therefore, is not a distinct tubular member but rather a ribbon used solely to couple a stent to a graft. This ribbon is furthermore wound circumferentially, and is therefore a circumferentially continuous body.

The present invention provides for a first tubular body and a second tubular body formed of elongate polytetrafluoroethylene strips arranged longitudinally in non-overlapping relationship. The second tubular body is perimetrically non-continuous. This type of tubular body is not disclosed in Ray.

The coupling member of Ray is a ribbon which is used to attach the stent to the graft, is helically wound circumferentially around the stent. See column 7, lines 52-55 of Ray.

The Examiner points to column 9, lines 17-20 of Ray which indicates the stent/graft may use "longitudinally extending strips of ribbon" as the coupling member. It is unclear however, in what tubular direction the longitudinally extending strips of ribbon are oriented. It is most probable that the longitudinally extending strips are wound in a helix. The full paragraph reads as follows:

Although a particular coupling member configuration and pattern has been illustrated and described, other configuration and/or patterns may be used without departing from the scope of the present invention. For example, coupling member(s) arranged in a multiple helix (e.g., a double or triple helix) may be used. Longitudinally extending strips of ribbon may be used and may be preferred when the coupling member is used in conjunction with other stent member configurations.

When taken in context of the entire disclosure, the use of the term "longitudinally extending strips of ribbon" seems to be referring to a strip of ribbon (as opposed to a continuous tape wrap) which has a **longitudinally extending shape**. It further appears that given the importance in the disclosure of a helically wound coupling member tracing the stent of Ray, that the longitudinal orientation is simply describing the physical characteristics of the ribbon, and is referring to longitudinally extending strips in the double helix configuration discussed in the relevant paragraph above. Further, the entire disclosure of Ray supports the use of a helically or

circumferentially wound coupling member. See Ray, column 6, line 15 - column 8, line 60.

This is further supported in each of the figures shown in Ray.

It would, therefore, not be an obvious improvement on Ray to employ the circumferentially non-continuous tubular member as claimed in the present invention. It is further suggested that the interpretation of the two lines of Ray upon which the Examiner basis the rejection under 35 U.S.C. §103 are not intended for the proposed meaning. If this passage were interpreted as suggested by the Examiner, it would, in fact, be contrary to the entire disclosure of Ray. Ray, therefore fails to render the present invention obvious.

The rejection based on 35 U.S.C. §103(a) is therefore respectfully traversed. Withdrawal of the rejection and reconsideration are respectfully requested.

The Examiner has also rejected claims 16 and 18 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,398,803 to Layne et al. More specifically, the Examiner states:

Layne et al. show first perimetrically non-continuous polytetrafluoroethylene inner tubular body (the inner "lacey" graft described in col. 5, lines 29-42), second perimetrically non-continuous outer tubular body (the outer "lacey" graft described in column 5, lines 29-42), support structure 30, both the outer and inner tubular body being formed of strips 48. Axial and radial compliance is obviously provided to the prosthesis due to the openings between the strips.

U.S. Patent No. 6, 398,803 to Layne et al. (hereinafter "Layne"), discloses a stent graft composite structure with an ePTFE tube with a "lacey" graft structure. The "lacey" structure of the tube is constructed by cutting apertures into an ePTFE tube. See Figures 2 and 3 of Layne. The ePTFE tube also may have slits as seen in Figure 4 of Layne.

The presently claimed invention provides a more compliant ePTFE tubular structure wherein there is no circumferential continuity in the ePTFE tubular structure. Figures 2 and 3 of Layne however, show that Layne in fact has circumferential continuity in its "lacey" graft. The apertures merely provide areas in the graft where it is discontinuous. The Layne ePTFE graft contains circumferential continuity.

Layne therefore discloses neither a first perimetrically non-continuous polytetrafluoroethylene inner tubular body nor a second perimetrically non-continuous outer tubular body as postulated by the Examiner. It would further not be an obvious addition to Layne to provide such a perimetrically non-continuous tubular body. It is stated in the summary of the invention that Layne is designed to provide an encapsulated stent wherein flexibility of the stent is retained despite encapsulation. See summary, column 1, lines 63-67 of Layne. It would therefore be contrary to the proposed disclosure of Layne to provide a perimetrically non-continuous tubular body as claimed in the present invention. Such a perimetrically non-continuous tubular body does not provide an encapsulated stent, as it is not wholly encapsulated by such a tubular body as it is in the embodiments of Layne.

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The rejection based on 35 U.S.C. §103(a) is therefore respectfully traversed. Withdrawal of the rejection and reconsideration are respectfully requested.

Should the Examiner have any questions or comments concerning this application or this amendment, he is invited to contact the undersigned counsel.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Mark E. Baron', is written over a horizontal line.

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